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Copenhaver et al.

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[54] **GASTROSTOMY FEEDING PORTS**

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[73] Assignee: **Wilson-Cook Medical, Inc.**, Winston-Salem, N.C.

[21] Appl. No.: **701,430**

[22] Filed: **Aug. 22, 1996**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 441,054, May 15, 1995, which is a continuation-in-part of Ser. No. 202,443, Feb. 28, 1994.

[51] **Int. Cl.**^{6} **A61M 5/00**

[52] **U.S. Cl.** **604/247**; 604/27; 604/48; 604/256

[58] **Field of Search** 604/247, 96, 27, 604/48, 277, 332, 256, 175

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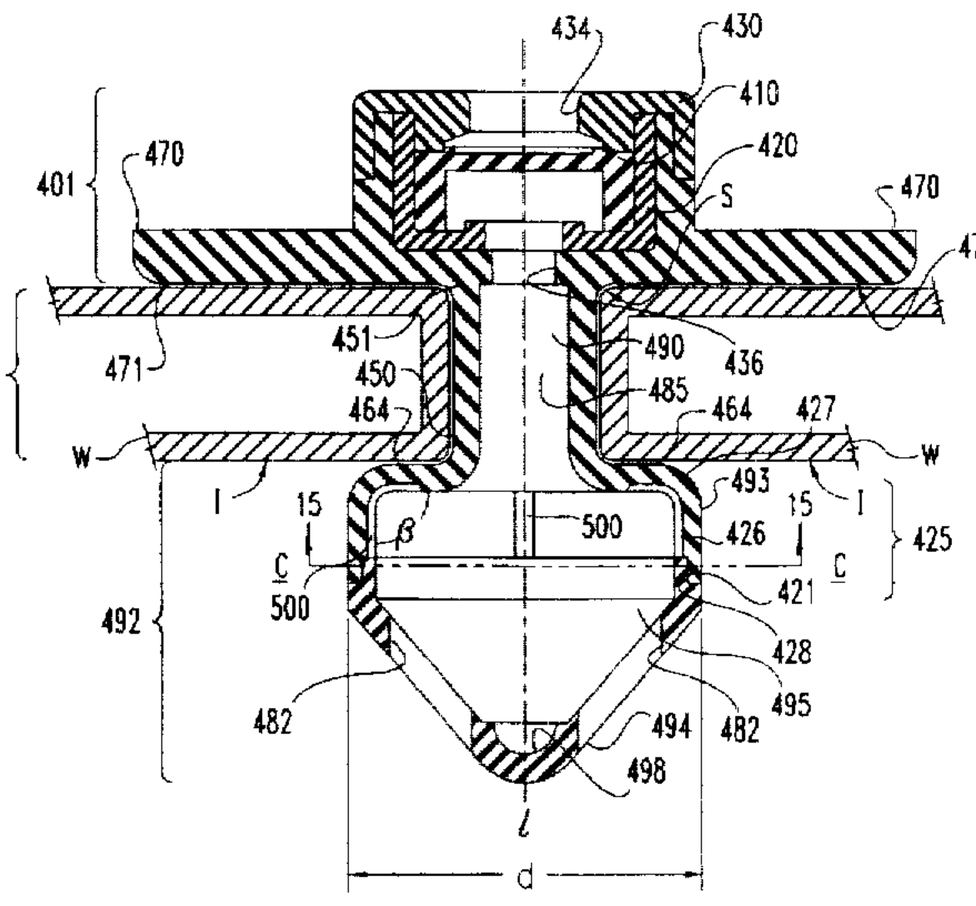
[57] **ABSTRACT**

Gastrostomy ports are disclosed for reliably providing enteral feeding to a patient over long periods of time. Gastrostomy ports shown herein provide one-way valves which include a resilient valve member which is compressively fitted within a receiving cavity defined by a rigid compression collar. The valve member has a diaphragm portion defining a slit. The compression collar presses inwardly against the outer peripheral edge of the diaphragm portion to apply laterally compressive forces which bias the slit toward a normally closed position. Gastrostomy ports are further shown for accessing the interior of a body cavity or organ which are self retaining and resist inadvertent pull-out but can be atraumatically implanted and removed. The devices include a retaining element which is resiliently deformable between a normally enlarged state for retention and a collapsed state for insertion and removal through a stoma and are provided with means for controllably biasing the element toward a longitudinal axis for collapsing the element. Still additional embodiments are disclosed which provide for the direct conversion of an implanted PEG tube into a low profile feeding port, and which further provide for the direct secure connection to an enteral feeding tube adapter.

13 Claims, 11 Drawing Sheets



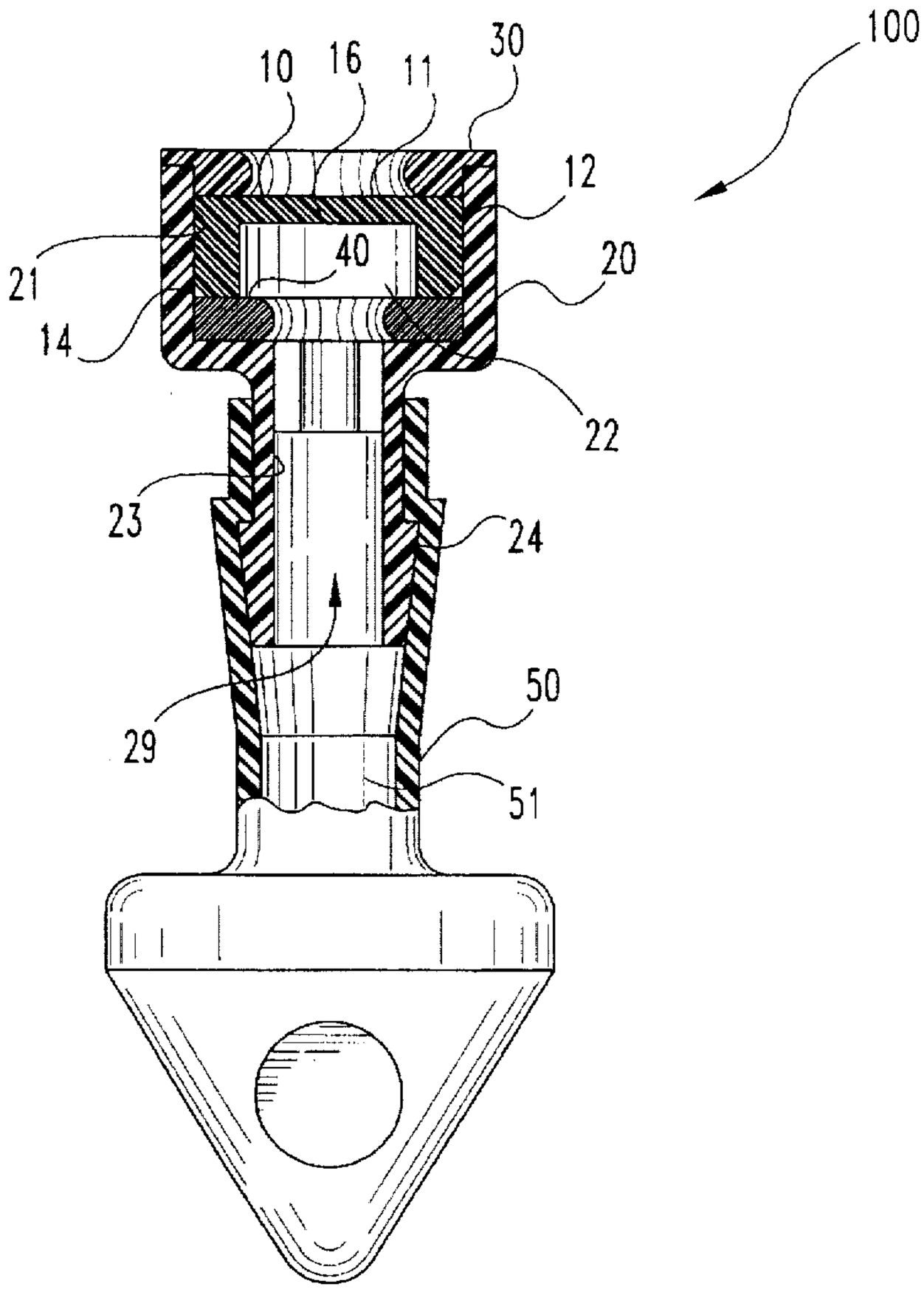


Fig. 1

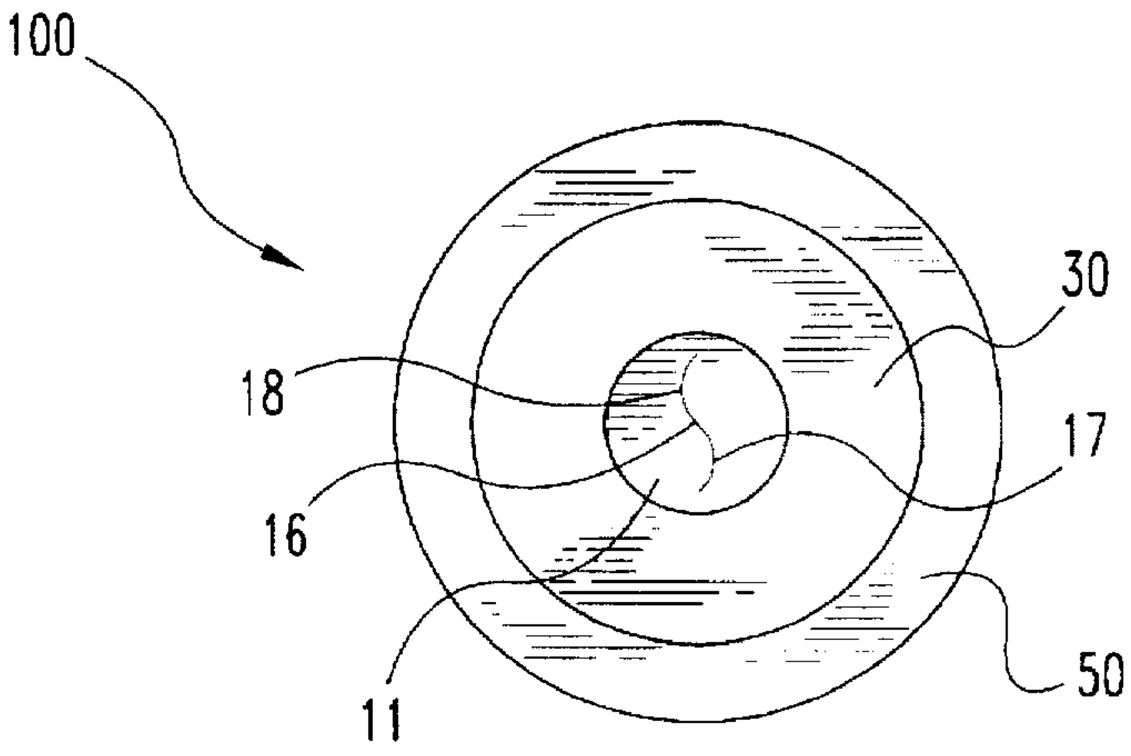


Fig. 2

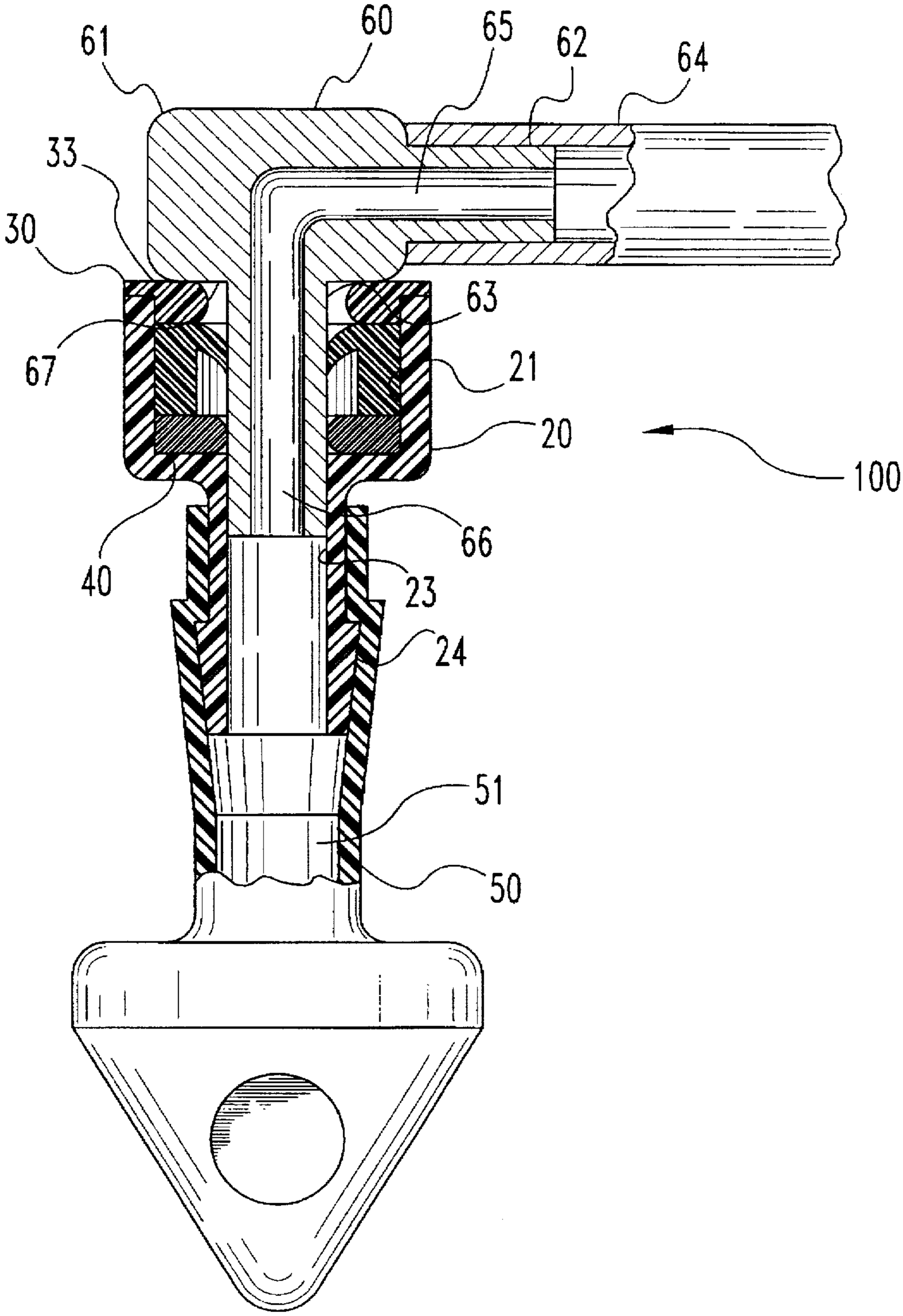


Fig. 3

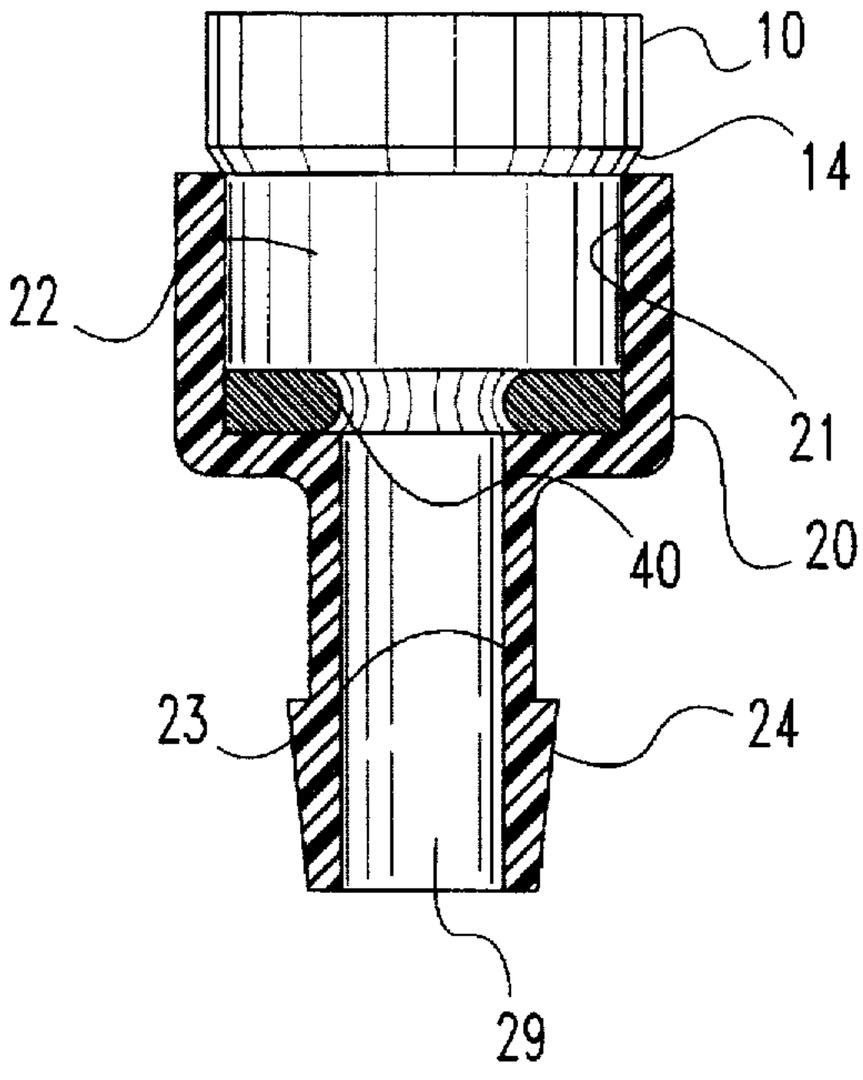


Fig. 4a

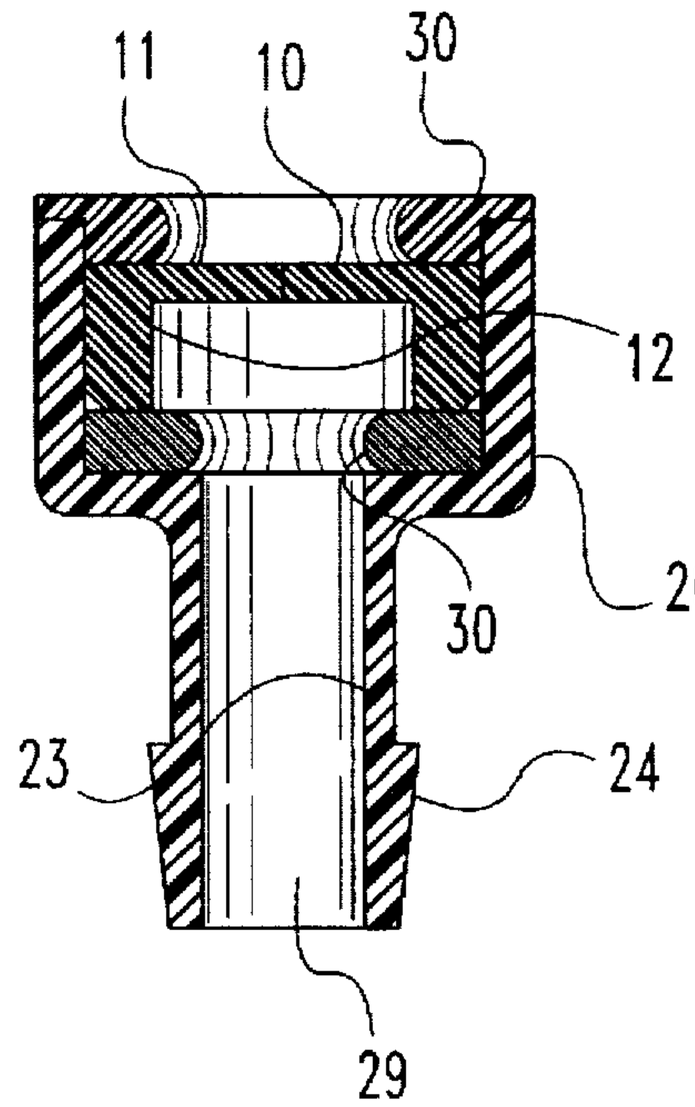


Fig. 4b

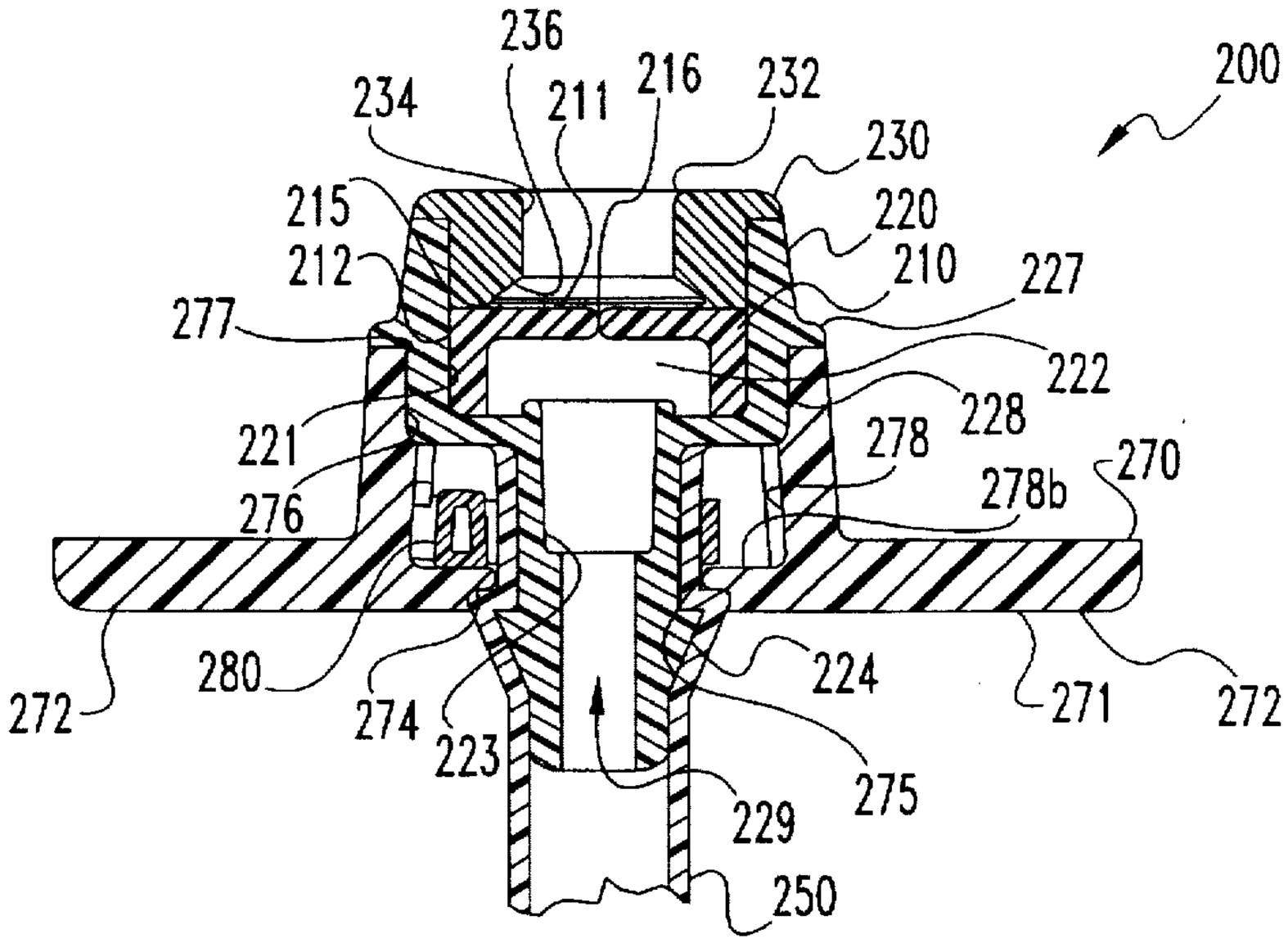

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Fig. 5

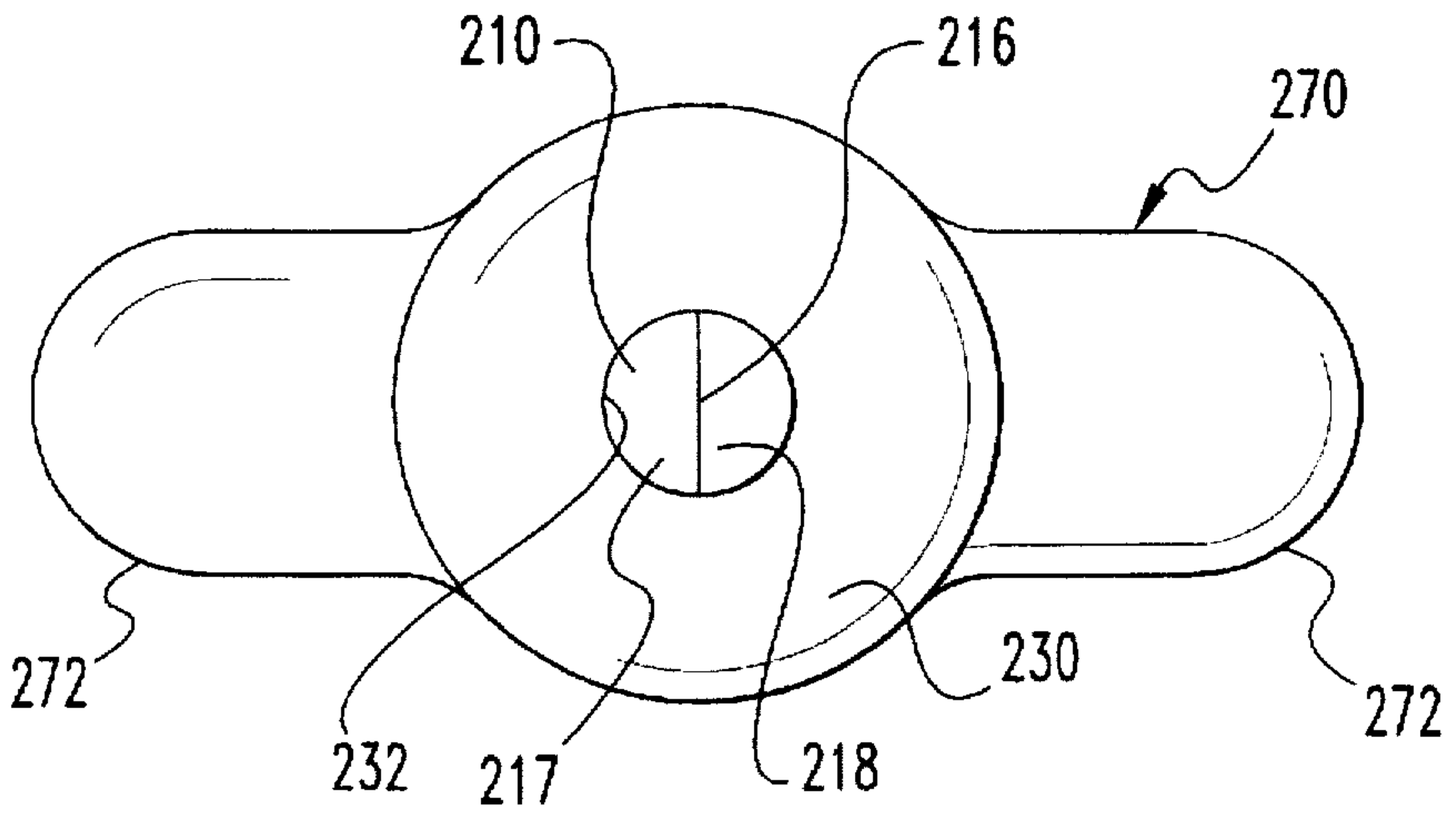
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Fig. 6

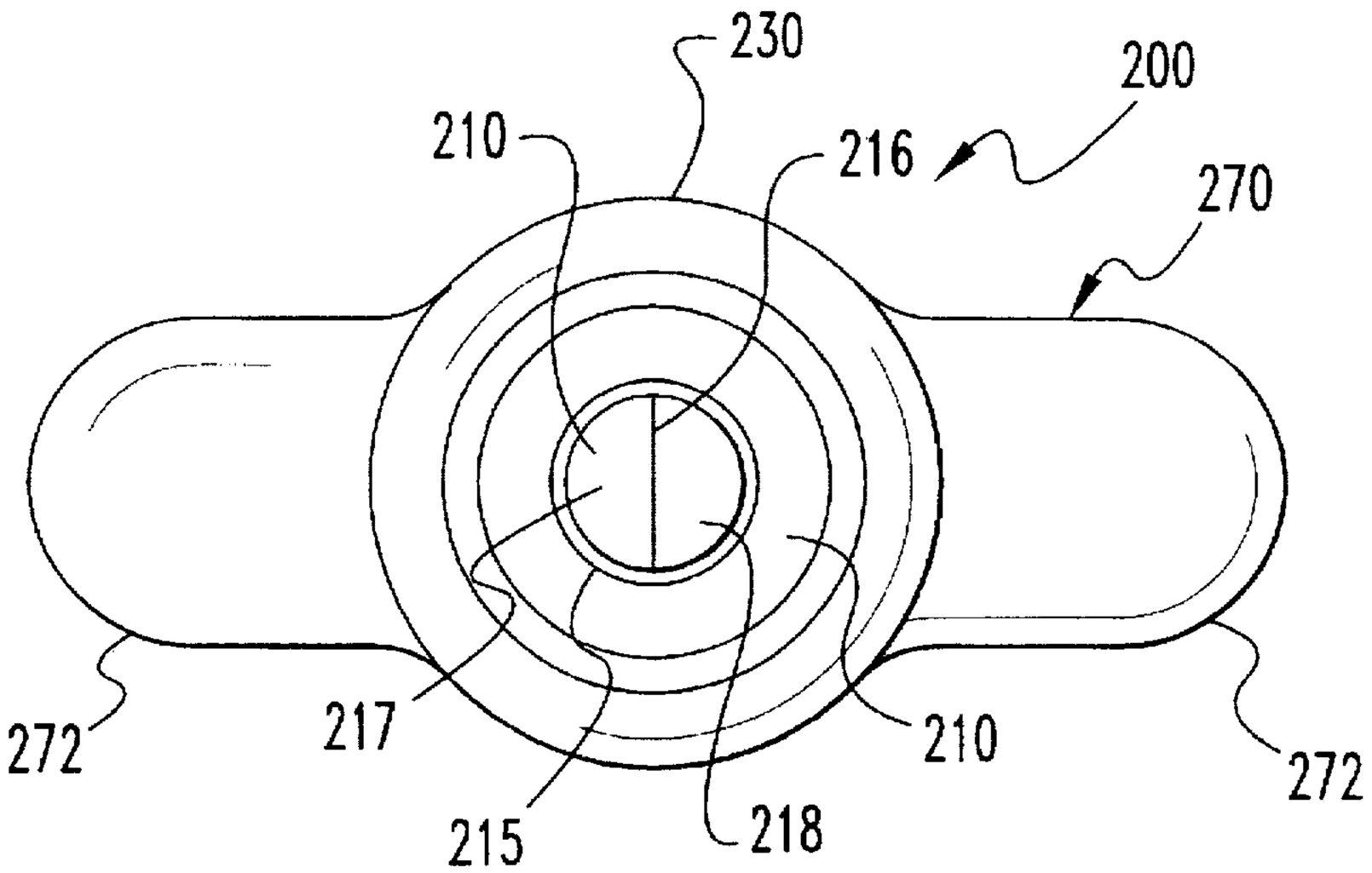
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Fig. 7

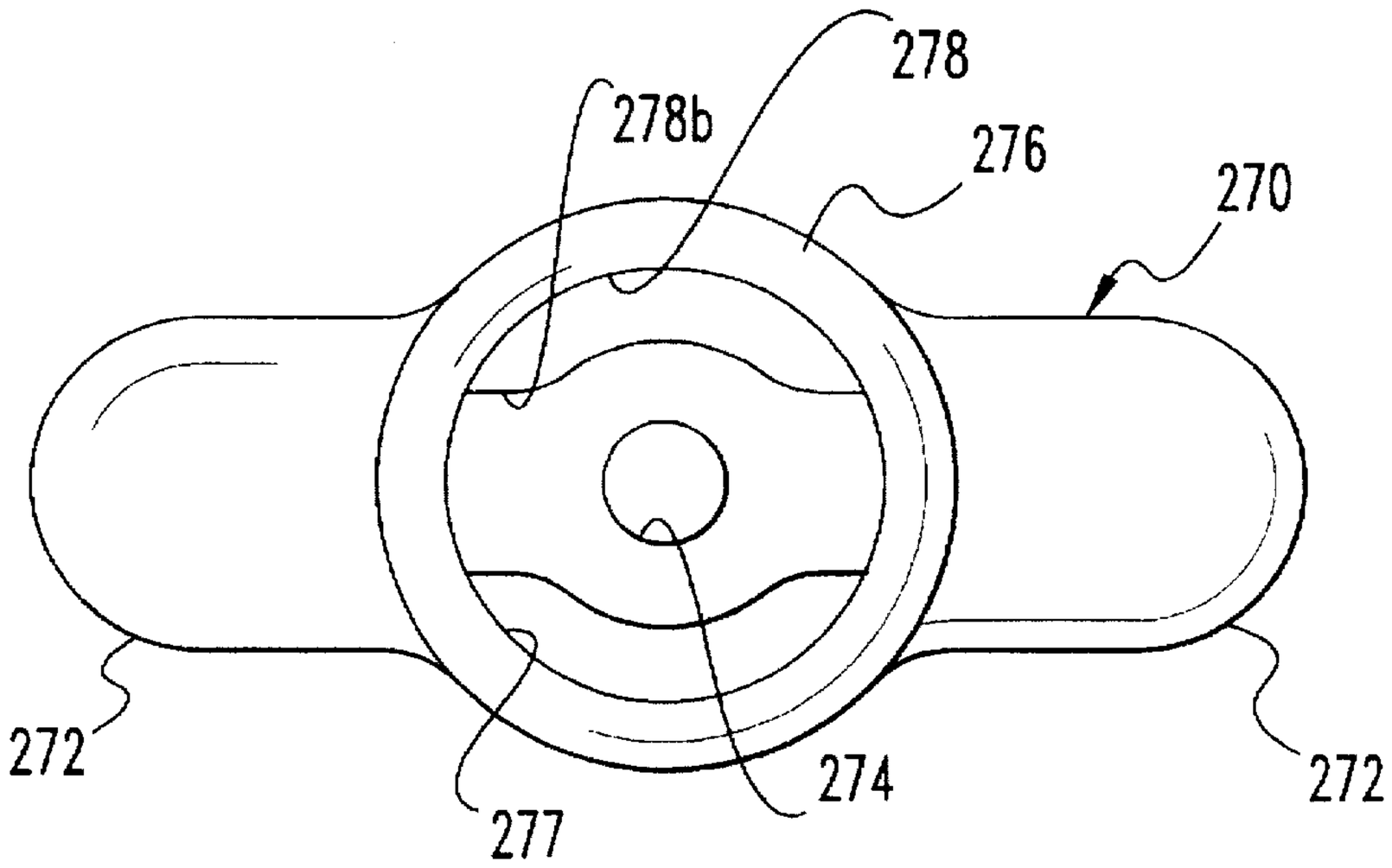
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Fig. 8

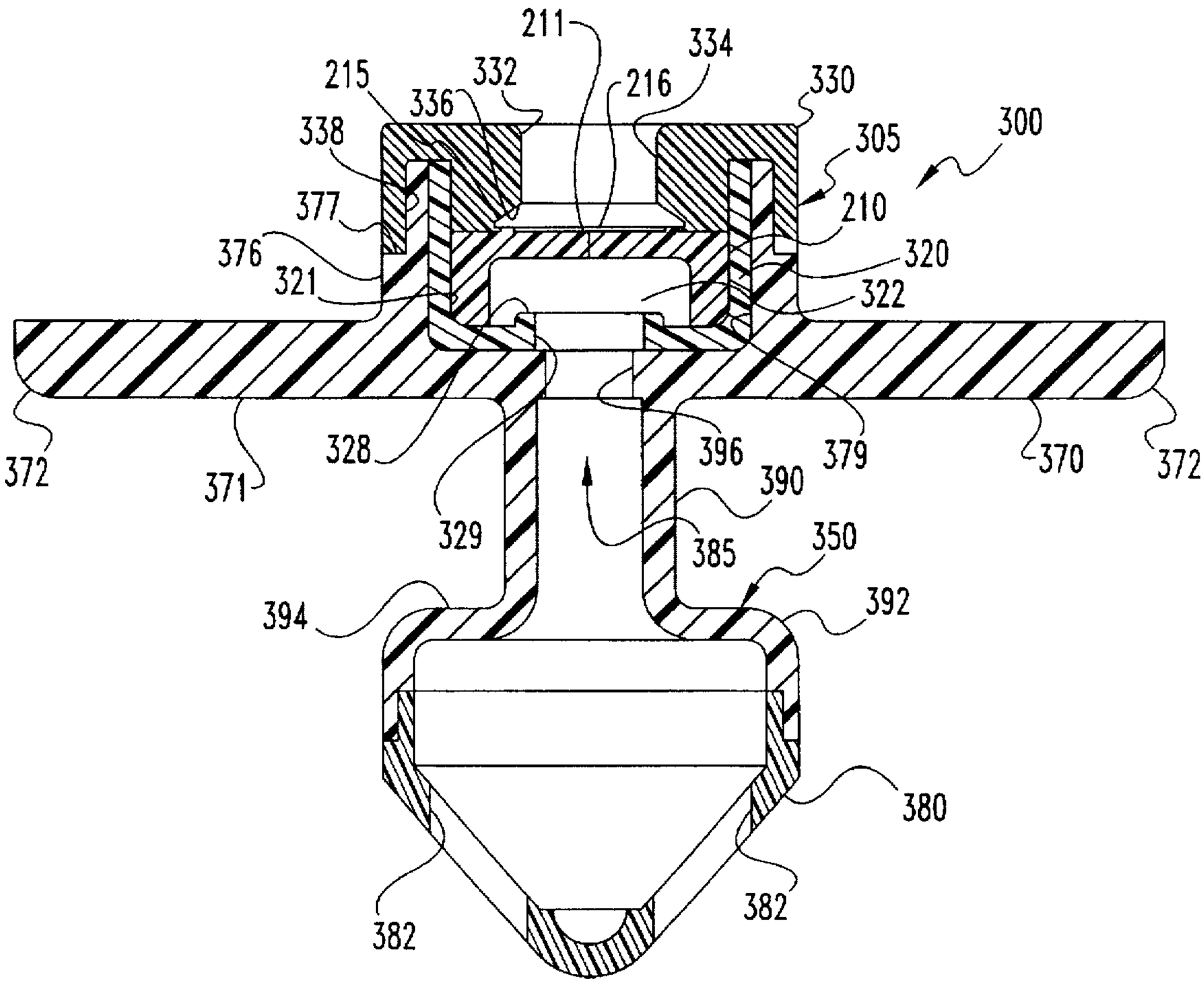
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Fig. 9

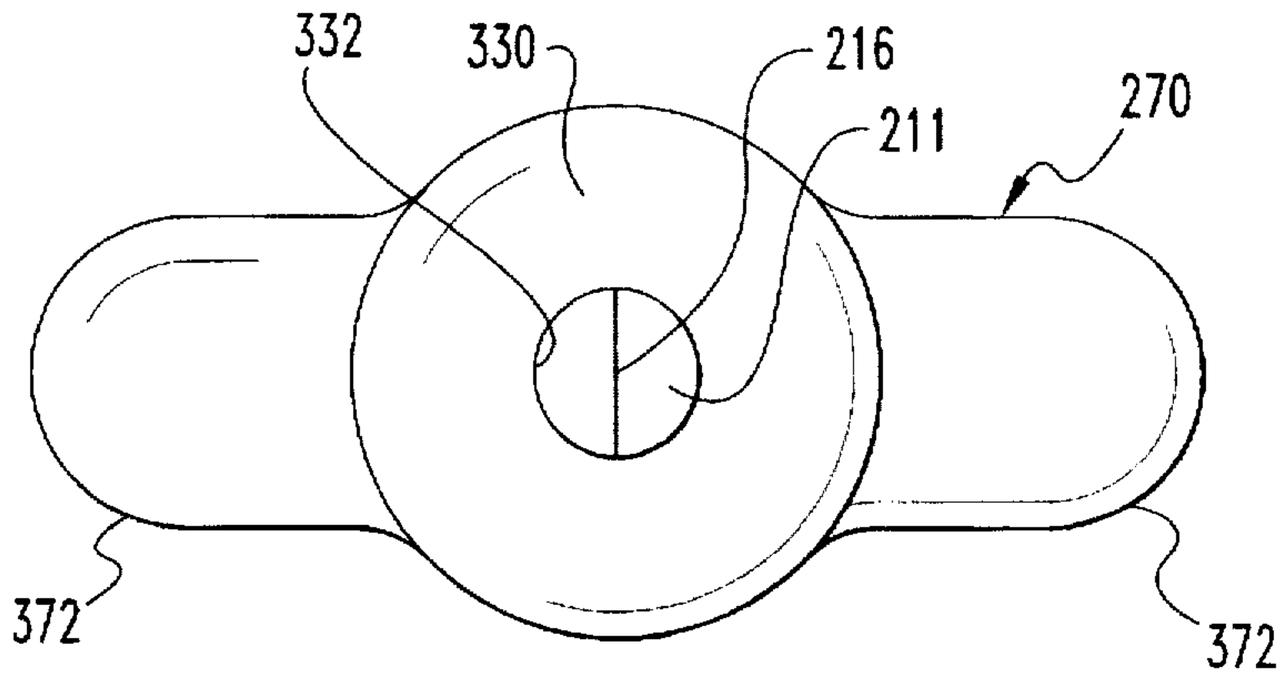
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Fig. 10

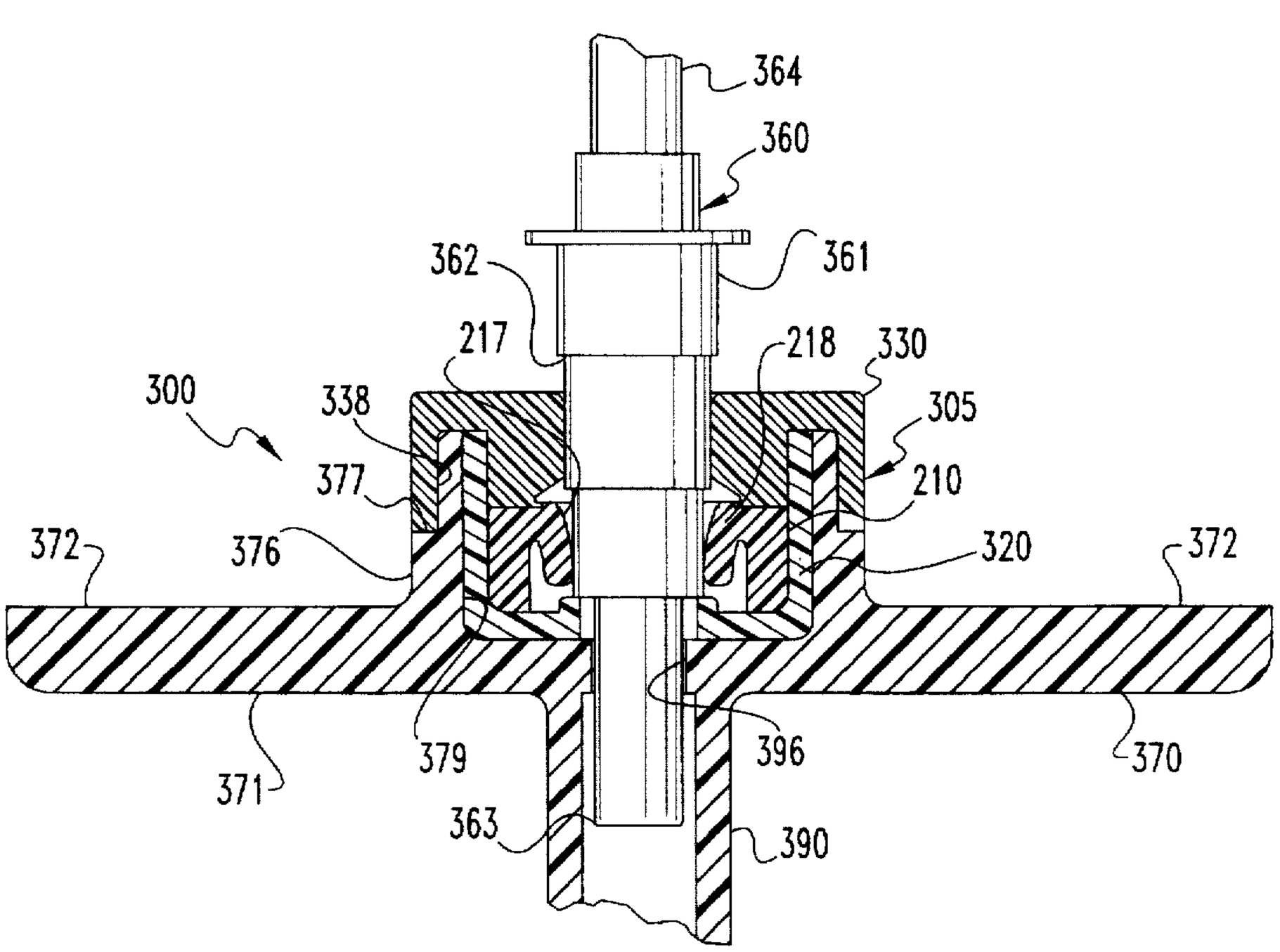
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Fig. 11

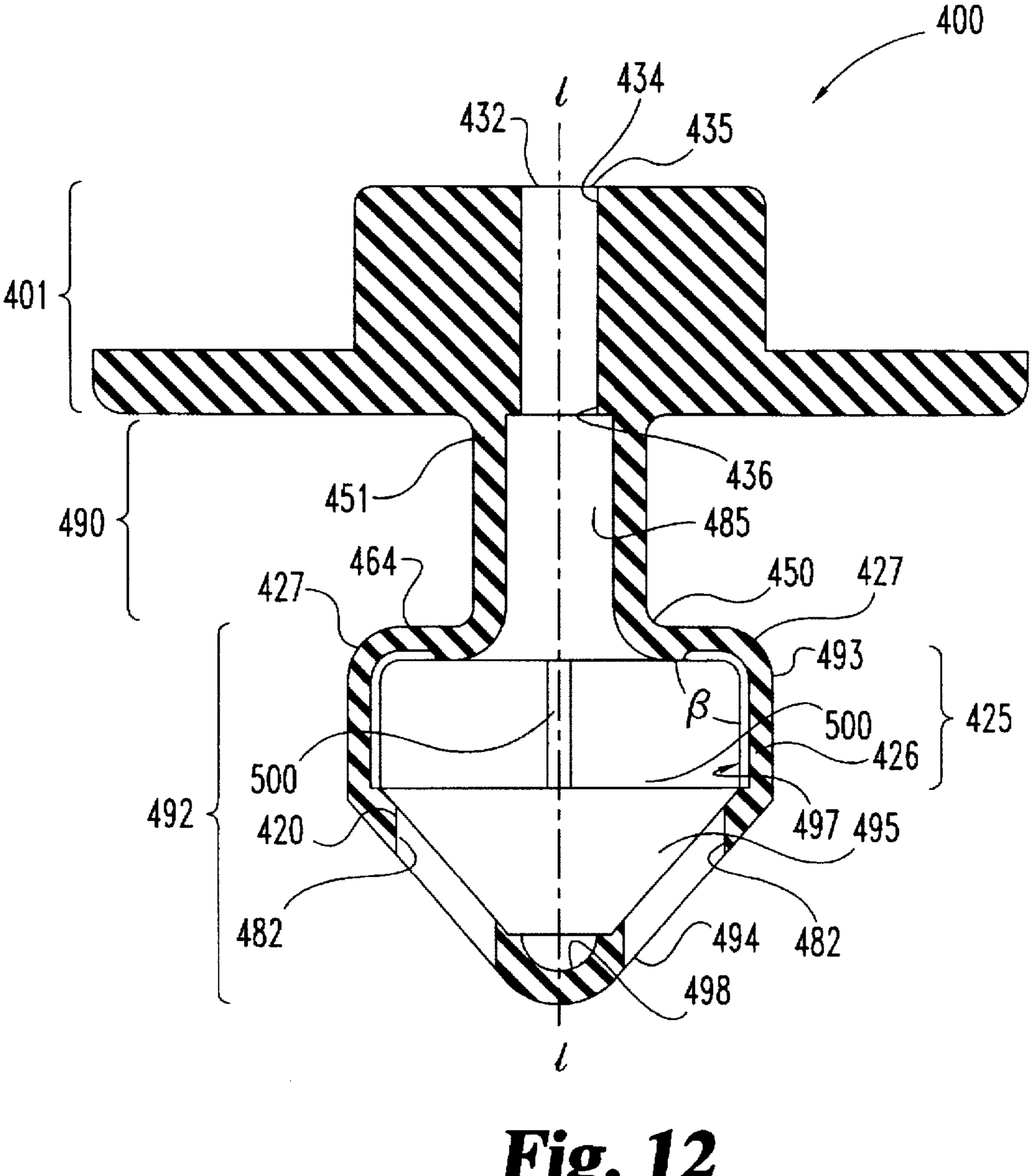
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Fig. 12

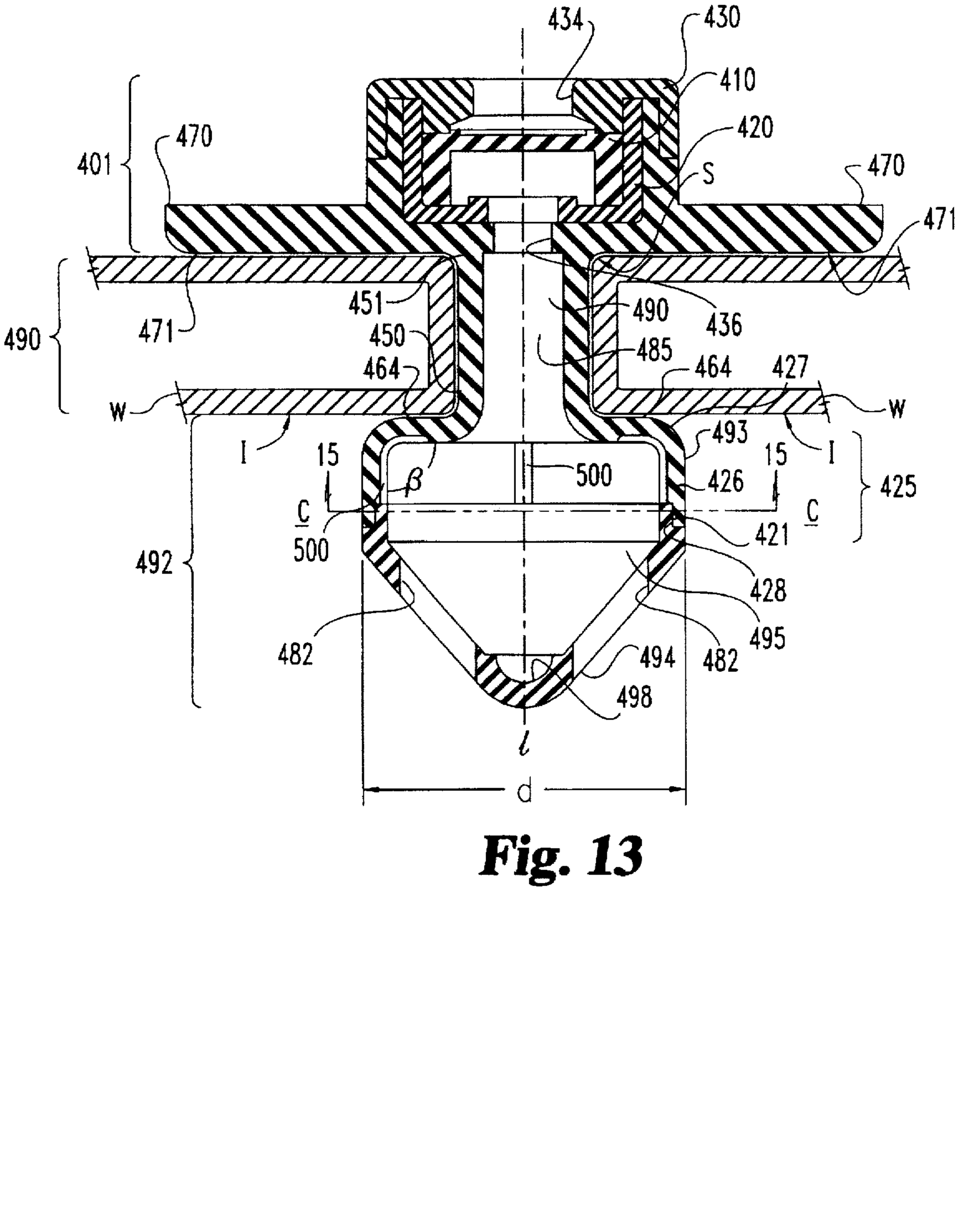
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Fig. 13

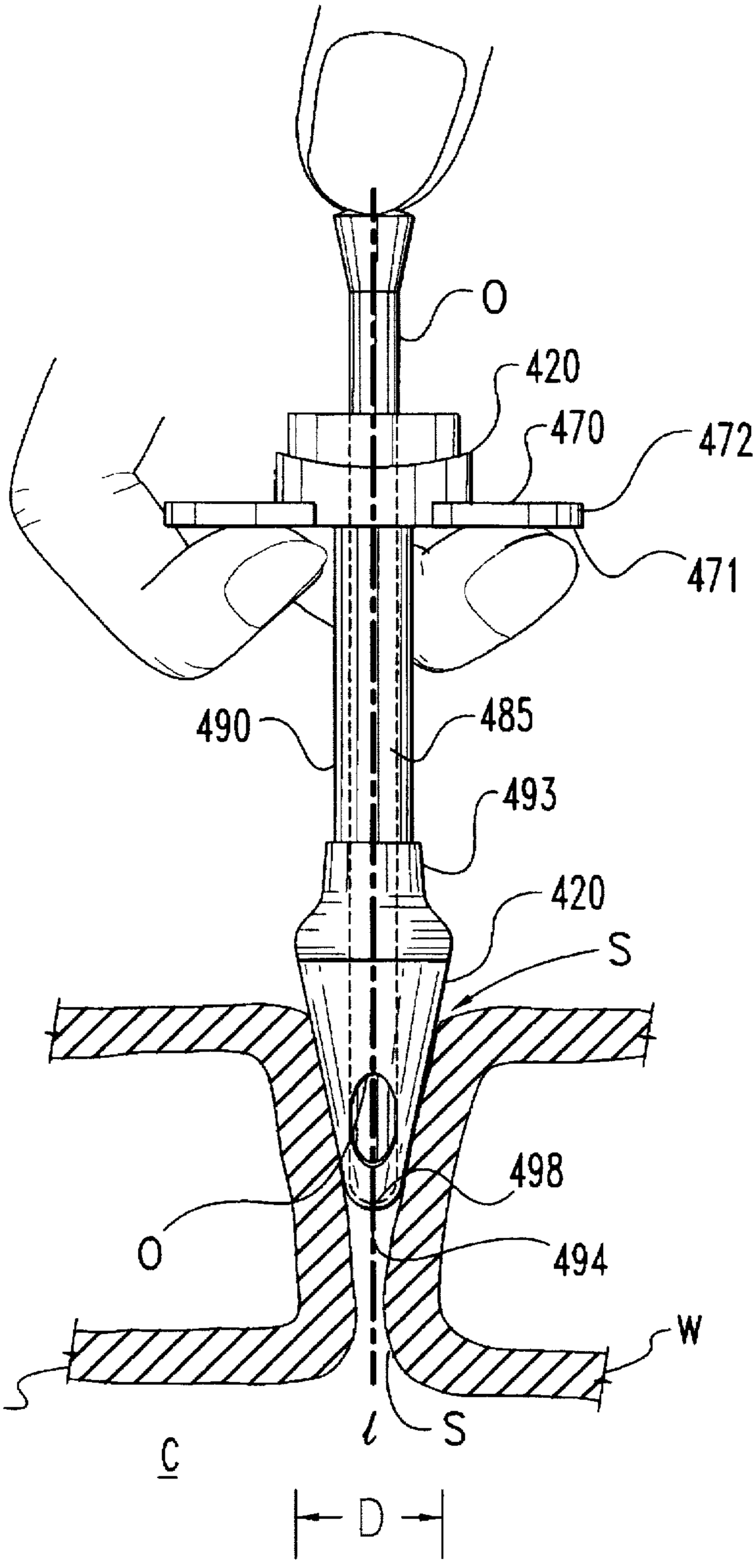

Fig. 14

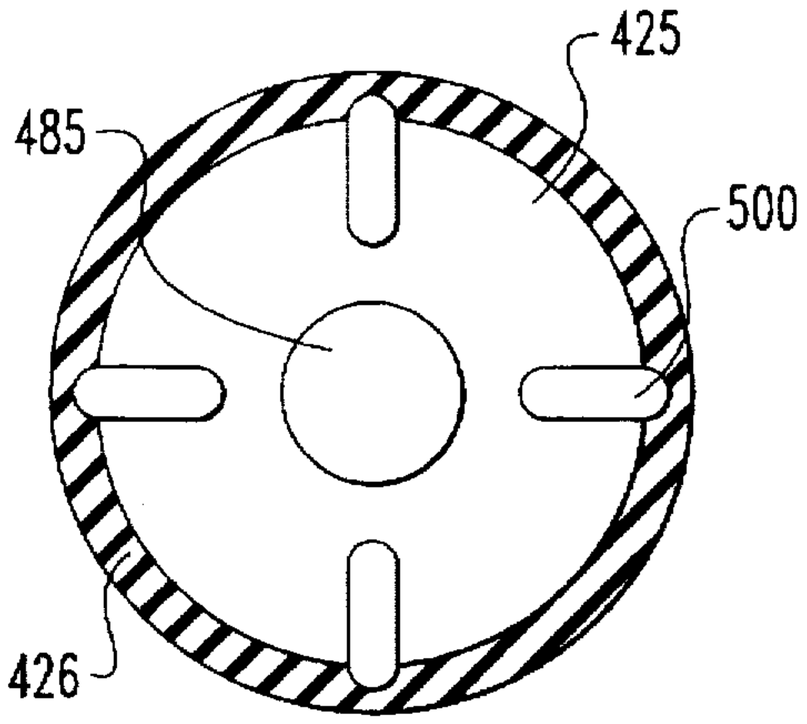

Fig. 15

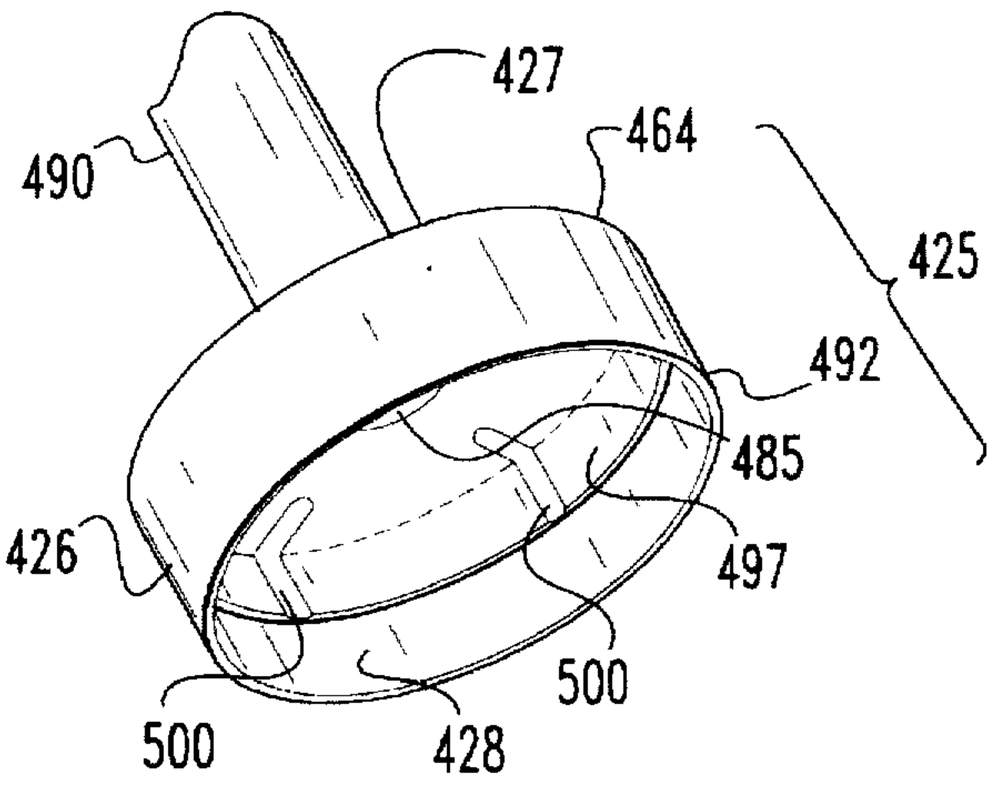

Fig. 16

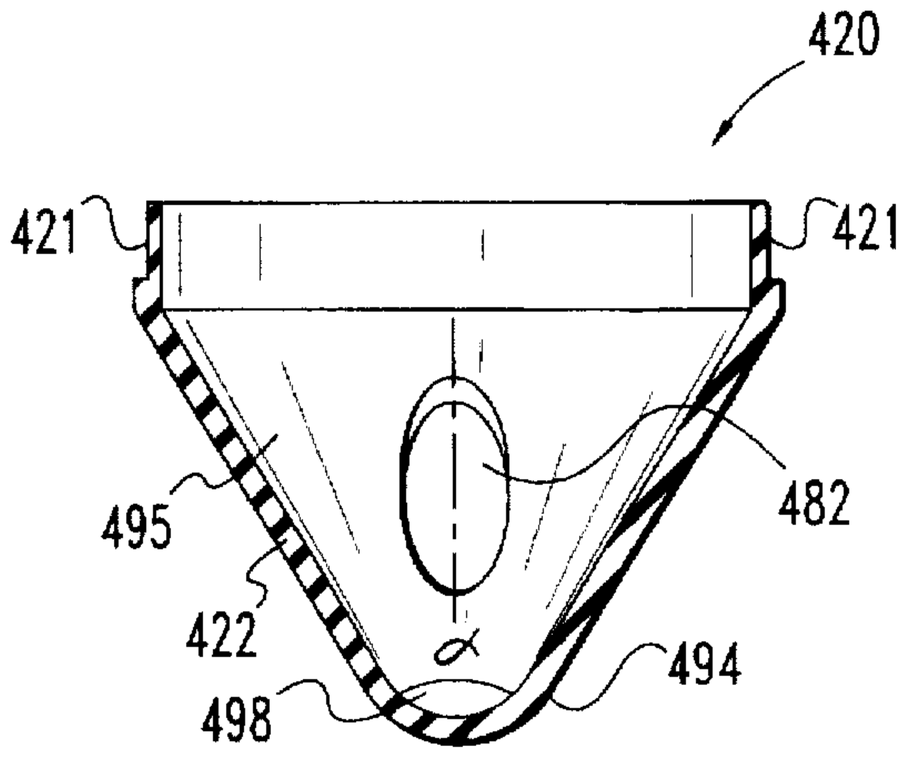

Fig. 17

GASTROSTOMY FEEDING PORTS

This is a continuation-in-part of application Ser. No. 08/441,054 filed on May 15, 1995, now pending which is a continuation-in-part of application Ser. No. 08/202,443 filed on Feb. 28, 1994 now pending.

FIELD OF THE INVENTION

This invention broadly relates to medical devices, and particularly relates to gastrostomy feeding ports.

BACKGROUND OF THE INVENTION

Gastrostomy feeding ports provide access to the stomach at a stoma site. Such ports are typically left in place over a prolonged period of time and are used for feeding and medicating the patient over this period. Gastrostomy feeding ports are usually low profile, fitting fairly flush to the skin surface to minimize patient discomfort, improve aesthetics and help to prevent unnecessary irritation to the stomal area. In the design of a long term implanted device such as a gastrostomy port several factors must be considered, such as biocompatibility and patient comfort as well as enhanced function of the device.

One problem with gastrostomy ports in particular is that the link they provide between the stomach and the exterior of the body creates a potential for leakage of gastric contents. This leakage or reflux of gastric contents is particularly troublesome because the highly acidic materials can cause severe skin burns or tissue maceration leading to chronic skin infections. This is complicated by the requirement that the port be used repeatedly over a long period of time which increases the potential for leakage. This requirement that a gastrostomy port prevent reflux while allowing convenient and repeated access to the stomach has presented a difficult design problem.

To address the need to prevent reflux while allowing convenient access through the device to the stomach, some gastrostomy ports include check valves. U.S. Pat. No. 4,944,732 discloses a device, commercially available as the Gastro-Port from Sandoz Nutrition Corp., that includes an anti-reflux valve located outside the body in a removable screw cap. Since the valve portion is removable it can be repaired or replaced as needed without replacing the entire feeding port. The Button Replacement Gastrostomy Device is another commercially available gastrostomy feeding port which includes an anti-reflux valve. In the Button device, the anti-reflux valve is located in the distal tip of the device inside the stomach.

As a long term indwelling catheter, a gastrostomy feeding port requires a positive seal for many repeated uses over a long period of time. Unfortunately, some of the prior art gastrostomy feeding port valves have failed to prevent reflux, particularly after many repeated uses. Consequently, some gastrostomy feeding ports, such as the Button and Gastro-Port devices, are supplied with closure caps which positively seal the port entrance while the port is not being used. Closure caps, however, are inconvenient because they must be removed prior to each use of the port and reapplied onto the port after each such use. Over the course of time that a single port is left in place, the cap must be removed and replaced hundreds of times. Should the cap be forgotten or not properly closed about the port even a single time, unintended leakage may consequently occur.

There is a need for a long term indwelling gastrostomy feeding port, with an entrance valve that provides a positive sealing effect over the course of many recurrent uses of the valve and over an extended period of time. Such a device would eliminate the need for a closure cap and would be both safer and more convenient to use than devices that have been provided in the past.

Prior to the implantation of a low profile gastrostomy port, it is common to implant a long, smooth walled Percutaneous Endoscopic Gastrostomy (PEG) tube for enteral feeding or medication. After a time, the PEG tube is removed and replaced with a low profile device, which is more convenient to the patient, especially when a bedstricken patient becomes able to resume a more mobile lifestyle. It is common to remove the PEG tube in its entirety and replace the PEG with a low profile device in the stoma site where the PEG tube had been. While it would be desirable to reduce the trauma and increased risk of infection resulting from completely removing the PEG tube by, instead, directly converting the PEG tube that has already been placed into a low profile device, the converting port device must securely and reliably attach to the PEG tube so that the connection does not loosen over the length of time that the port is left in place. Accordingly, there is a need for a device which directly converts a long PEG feeding tube into a reliable low profile gastostomy feeding port. The conversion should be easy to accomplish and provide for the reliably secure connection of the valve mechanism to the implanted PEG tube.

There is a further need to provide a gastrostomy port device which provides for the securely sealed direct connection to a standard enteral feeding adapter. Such a port would be more convenient as it would remove the need to use intermediate tubing connections.

Gastrostomy ports should also be reliably self-retaining over the long period of time that they may be left in place on a patient. For this purpose, gastrostomy ports commonly include an enlarged retaining structure for placement within the stomach to keep the port in its desired location. The retaining structure contacts the internal surface of the stomach wall surrounding the stomal opening to resist inadvertent pull-out of the device.

To reduce the trauma of insertion into and removal from a stomal site, some devices have included inflatable/deflatable balloon elements which can be inflated through an inflation lumen as disclosed in U.S. Pat. Nos. 5,342,321 to Potter and 5,125,897 to Quinn et al. Other references disclose restraining an enlarged deformable element with pressure on the external surface of the element to collapse the element. U.S. Pat. No. 4,315,513 to Nawash et al. discloses a deformable retaining element which is elongated and compressed into a biodegradable material which will dissolve in the stomach thus allowing expansion of the retaining element. Using a similar approach, Michels et al. discloses inserting a port having a deformable retaining element with a trocar. The retaining element can be collapsed within a semi-rigid casing and inserted into the trocar for placement through the stoma. The casing is removed from the element to allow expansion once it is inserted within the stomach.

Other references disclose deforming a retaining element by insertion of an obturator or similar device. For example, U.S. Pat. Nos. 4,863,438 to Gauderer et al. and 4,944,732 to Russo disclose an enlarged retaining element which is deformable to a collapsed state by the insertion of an obturator for insertion through the stoma. Once the retaining element passes through the stoma the obturator can be removed allowing the retaining element to assume an enlarged state.

Some devices have been designed with areas of decreased thickness in the retaining element to enhance the collapsability of the retaining element during insertion or removal of the device. U.S. Pat. No. 5,336,203 to Goldhardt et al. discloses one such gastrostomy device in which the sidewall of a domed retaining element is thinned to enhance the collapsability of the device. U.S. Pat. No. 5,356,391 to Stewart discloses a gastrostomy tube having reinforced areas over portions of a hemispherically shaped retaining flange to enhance the collapsibility of the flange for atraumatic removal of the device. While enhancing collapsibility, these devices also have lessened resistance to inadvertent pull-out. A need remains for new devices which can be atraumatically inserted and removed through a stoma but which are also structured to reliably resist inadvertent pull-out.

SUMMARY OF THE INVENTION

The present invention generally provides new and useful medical devices which are particularly useful for long-term enteral feeding of a patient.

By one aspect of the present invention, there is provided a long term indwelling catheter with an improved one-way entrance seal module which will remain positively sealed closed after repeated and extensive use. The improved seal is especially useful when used as part of a low profile enteral gastrostomy feeding port where the valve and port might be left indwelling in a patient for up to a year and where a positive seal must be maintained even after hundreds of repeated uses.

The seal module includes a valve housing and a resilient valve member contained therein. The valve housing defines an inner passageway to provide fluid communication into a long term indwelling catheter and includes a rigid compression collar portion which defines a valve member receiving cavity within the inner passageway. In one aspect, the resilient valve member has a diaphragm portion which has an "S" shaped slit therein and an outer peripheral edge which generally conforms in shape to the valve member receiving cavity but is larger in dimension than the cavity when uncompressed. The resilient valve member also includes an outer wall portion which extends away from the outer peripheral edge of the diaphragm portion and which generally conforms in shape to the cavity. The resilient valve member is compressively fitted within the receiving cavity by the advancing of the outer wall portion into said cavity to thereby cause the outer peripheral edge to be compressed in dimension to fit within the cavity, with the compression collar pressing inwardly against the outer peripheral edge of the diaphragm portion to apply laterally compressive forces which bias the slit toward a normally closed position.

The resilient valve member is made of a one-piece resiliently molded valve with a flat membrane. The "S" shaped slit therein is formed by two arcically shaped leaves. The valve member is cylindrically shaped and is compressively fitted into the likewise cylindrically shaped compression collar to bias the arcical leaves to a positively sealed closed position. Feeding adapters can be repeatedly inserted through the valve and connected directly with the catheter lumen to deliver unobstructed enteral formula directly into the patient. Removal of the adapter returns the valve immediately to its positively sealed position due to the compressive forces of the collar about the arcically shaped leaves.

The valve remains compressively biased towards its sealed closed position when not in use, and is not permitted to stretch or deform which can lead to leakage. The one-way entrance seal permits convenient insertion of an obturator to help in insertion of the catheter into the body and the seal also permits convenient insertion of a feeding adapter which can be used for either feeding or decompression of the stomach. It needs no separate closure plug, or removal of a screw cap, or different feeding adapters, or complicated decompression tubes. This valve structure allows the device to be lower in profile and closer to the skin surface, and helps to make the device more convenient, less complicated, and easier to use than other devices in the prior art. The device is especially useful for active children who require low profile feeding ports.

Briefly describing another aspect of the present invention, ports are provided for accessing the interior of a body cavity or organ which is self retaining and resist inadvertent pull-out but that can be atraumatically implanted and removed. The devices include a retaining element which is resiliently deformable between a normally enlarged state for retention and a collapsed state for insertion and removal through a stoma and are provided with means for controllably biasing the element toward a longitudinal axis for collapsing the element.

A gastrostomy port device includes a port head defining a passageway having a first end and a second end and an entrance in communication with the first end of the passageway for receiving a delivery device. A hollow tubular stem portion having an inner end and an outer end is attached to the port head. The stem portion defines a lumen in communication with the second end of the passageway. The stem portion is sized to extend through the stoma with the port head disposed on the exterior of the patient. A retaining element is provided which has a first end attached to the inner end of the stem portion and a second end. The element defines a cavity in communication with the lumen and a hole in communication with the cavity for delivering materials to the interior of the body cavity. The element also has an interior surface defining a tool engaging surface at the second end of the element for engaging an insertion tool that passes through the lumen. The element is resiliently deformable between a normally enlarged state for retention and a collapsed state for insertion and removal through the stoma. The element includes a support surface at the first end configured for contacting the internal surface of the body cavity to retain the element within the body cavity when the stem portion is inserted through the stoma and the element is in its normally enlarged state.

In one feature of the invention, the interior surface of the element defines a first groove substantially parallel to a longitudinal axis defined by the cavity. The first groove is configured to controllably bias the folding and collapsing of the retaining element toward and generally parallel to the longitudinal axis when the insertion tool is engaged to or pressed against the tool engaging surface for insertion through the stoma.

Additional embodiments are disclosed which provide for the direct convertion of an implanted PEG tube to a low profile long term feeding device, and which further provide for the direct secure connection to an enteral feeding adapter without the need for an extension tube as an intermediate connector.

Accordingly, it is an object of the present invention to provide improved one-way entrance seals for medical catheters and gastrostomy feeding ports.

Another object of this invention is to provide a securely self-retaining gastrostomy port which can be atraumatically implanted and removed.

Still another object of the invention is to provide a low profile gastrostomy feeding port which incorporates a one-

way seal and which provides for the securely sealed direct connection to an enteral feeding adapter.

Another object of the present invention is to provide a gastrostomy feeding port which is less complicated, easier to use, and less expensive than other commercially available products.

One advantage of this invention is that it provides self-retaining, atraumatic and anti-reflux features without the cumbersome and inconvenient aspects of prior devices.

Another object of the invention is to provide an improved gastrostomy feeding device utilizing a one-way seal that usefully converts an implanted PEG tube into a low profile feeding device.

Other objects, features, and advantages of the invention shall become apparent from the detailed drawings and descriptions which follow.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side, partially cross-sectioned view of a gastrostomy port of the present invention incorporating a positively sealing one-way entrance valve.

FIG. **2** is a top plan view of the gastrostomy feeding port of FIG. **1**.

FIG. **3** is a partially cross-sectioned side view of the gastrostomy feeding port of FIGS. **1** and **2**, showing a right angle adapter opening the one-way entrance seal and seated within the valve module to provide access into the catheter lumen of the feeding port.

FIG. **4***a* is a side cross-sectioned view of the valve housing of FIGS. **1–3**, showing resilient valve member **10** prior to positioning within cavity **22**. FIG. **4***b* is a side cross-sectioned view of valve housing **20** of FIG. **4***a*, showing resilient valve member press fitted into cavity **22**, with retainer cap **30** mounted thereon to maintain valve member **10** within cavity **22**.

FIG. **5** is a side, cross-sectioned view of a second embodiment of the present invention which usefully converts an implanted PEG feeding tube into a low profile device, and which also directly connects to an enteral feeding adapter without the need for intermediate extension tubing.

FIG. **6** is a top plan view of the gastrostomy port shown in FIG. **5**.

FIG. **7** is a top plan view of the gastrostomy port shown in FIG. **5** with the cap removed.

FIG. **8** is a top plan view of the bolster included in the embodiment shown in FIG. **5**.

FIG. **9** is a side, cross-sectioned view of a third embodiment of a unitary, fixed length, low profile gastrostomy port of the present invention which directly connects to an enteral feeding adapter without the need for intermediate extension tubing.

FIG. **10** is a top plan view of the gastrostomy port shown in FIG. **9**.

FIG. **11** is a partially cross-sectioned side view of an enteral feeding adapter directly connected to the gastrostomy feeding port of FIGS. **9** and **10**.

FIG. **12** is a side, cross-sectioned view of one embodiment of a port having a retaining element implanted within a stoma.

FIG. **13** is side, cross-sectioned view of a port having a one-way valve and a self-retaining element implanted within a stoma.

FIG. **14** depicts the implantation of the port depicted in FIG. **13** in the collapsed state using an obturator.

FIG. **15** is an end cross-sectional view of the retaining element depicted in FIG. **13** taken along lines **15—15**.

FIG. **16** is a bottom cross-sectional view of a portion of the device shown in FIG. **13**.

FIG. **17** is a front cross-sectional view of the tip of the retaining element depicted in FIG. **13**.

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated devices, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring now to FIGS. **1** and **2**, there is shown a gastrostomy feeding port **100** which includes resilient valve member **10**, valve housing **20**, retainer cap **30**, o-ring seal **40**, and tubular/tip member **50**. Resilient valve member **10** is made of silicone rubber, and has been constructed as a molded one-piece component and is preferably made from shore A 50 to 60 durometer high tear strength medical grade silicone. Diaphragm portion **11** of valve **10** is about 0.050 inches thick and about 0.325 inches in diameter and has a centrally located S-shaped slit **16** therein. Valve member **10** further has an outer cylindrical wall portion **12** which extends downwardly from the peripheral edge of diaphragm portion **11**. O-ring **40** is preferably made of medical grade silicone as well, in the range of shore A 60 to 65 hardness.

Valve housing **20** defines an inner passageway **29** therethrough and includes rigid compression collar portion **21** which defines receiving cavity **22**, annular seating portion **23** for seating of an adapter, and annular barb **24** for securing attachment to tubular/tip member **50**. Valve housing **20** is injection molded from a rigid plastic such as lexan or polypropylene, but could be a machined part of stainless steel, or made of other suitable biocompatible material as well. Retainer cap **30** is preferably made of the same material as valve housing **20**.

To assemble the valve structure for gastrostomy port **100**, o-ring seal **40** is first placed into cavity **22** defined by compressive collar portion **21** of valve housing **20**. Valve member **10** is then "press" fit into valve housing **20** by first fitting outer cylindrical wall portion **12** of valve member **10** into compression collar **21** and then applying even pressure to advance valve member **10** into cavity **22**. The lower portion of cylindrical wall portion **12** of valve member **10** has a chamfered edge **14** to facilitate the introduction of valve member **10** into cavity **22**. Also, isopropyl alcohol, which readily evaporates, can be used as a lubricant to aid in the press fitting of valve member **10** into valve housing **20**.

As valve member **10** is advanced into cavity **22**, cylindrical wall portion **12** is compressed to conform to the size of cavity **22**. The compression of cylindrical wall portion **12**, in turn, applies an evenly distributed compressive force on diaphragm portion **11** to cause diaphragm portion **11** to be evenly compressed and to thereby fit within cavity **22** without buckling or distorting. Once valve member **10** has been fully seated into valve housing **20**, compression collar **21** acts with an inwardly directing compressive force to actively bias leaves **17** and **18** of "S" slit **16** on diaphragm portion **11** to positively seal valve member **10**.

After valve member **10** has been seated into cavity **22**, retainer cap **30** is placed on the top portion of valve housing **20** and affixed thereto. Attachment may be made by use of a suitable biocompatible solvent cement, or by ultrasonic welding. Once in place, retainer cap **30** does not exert any axial compressive force upon valve member **10**, which could cause distortion of the sealing arrangement, and preferably only rests on the surface of diaphragm portion **11** or allows for a small gap therebetween.

Compression collar **21** supplies an interference fit of 0.015 inches around the entire circumference of cylindrical wall portion **12** and thus exerts an even sealing pressure on the S-slit **16** at all times. Compression collar **21** exerts this constant pressure or pre-load on leaves **17** and **18** to prevent diaphragm portion **11** from stretching or losing its resiliency when the valve is repeatedly opened or closed. Once assembled as described above, gastrostomy port **100** becomes one unitized piece with a one-way entrance valve seal accessing the central lumen of the tubular/tip member **50**. The one-way valve permits only entrance into central lumen **51** and prevents any fluid from refluxing or backing up the tube and out the entrance seal.

FIG. **3** shows right angle adapter **60** opening entrance "S" slit **16** of valve member **10**. Adapter **60** has a rigid injection molded right angle body portion **61**, with rear stem **62** and front stem **63**. Connected onto rear stem **62** is flexible PVC connecting tube **64**. Rear stem **62** has lumen **65** and front stem **63** has lumen **66**. When front stem **63** opens entrance seal **10**, it seats into annular seating portion **23** of housing member **20**. The underside surface **67** on right angle body portion **60** seats firmly on top surface **33** of retainer cap **20**. So positioned, lumen **66** of front stem **63** accesses central lumen **51** of tubular/tip member **50**. Right angle adapter **60** thus accesses lumen **51** of tubular/tip member **50** to deliver enteral formula or the administration of liquid medication into the body of a patient.

Adapter **60**, via connecting tube **64**, can be attached to any medication or enteral delivery set whether administered by gravity or a pump delivery method. In addition, adapter **60** can act as a decompression tube to vent gastrostomy port **100** and relieve pressure build up which tends to occur when a gastrostomy feeding port is left in place over a long period of time. When not in use, adapter **60** is removed and valve member **10** closes instantaneously to prevent reflux. Sealing is instantaneous due to compression collar **21** which acts to positively return leaves **17** and **18** to their normally closed position. Adapter **60** can be repeatedly inserted as needed over many months of use without the valve leaking or stretching out of shape.

As described above, a right angle adapter can be inserted into the valve S-slit **16** as needed. The valve remains in its normally closed positively sealed position due to compressive collar **21** acting to bias valve member **10** closed and keeping it closed to prevent reflux of stomach contents out through valve member **10**. As such, feeding port **100** requires no internal anti-reflux valve, which might become clogged or stuck. It also does not need any removable valve cap or any stoppers or back up closure caps to add bulk to the outside profile. All functions can take place directly through the entrance seal, thus eliminating the need for anti-reflux valves, valve caps, stoppers, closure caps, or complicated decompression tubes.

FIG. **4***a* shows resilient valve member **10** prior to positioning within cavity **22**. In FIG. **4***a*, valve member **10** is uncompressed and is larger in dimension than cavity **22**. FIG. **4***a* further shows how chamfered edge **14** allows for the introduction of cylindrical wall portion **12** into cavity **22** such that valve member **10** can then be press fit into cavity **22** without buckling or distorting diaphragm portion **11**. FIG. **4***b*, showing resilient valve member **10**, after it has been press fitted into cavity **22**, with retainer cap **30** mounted thereon to maintain valve member **10** within cavity **22**.

A second embodiment of the present invention is illustrated in FIGS. **5**, **6** and **7** by which a long smooth walled PEG tube that has been previously implanted into a patient can be directly converted to a low profile gastrostomy port. By this conversion, the need to remove the PEG tube and install a separate low profile port is eliminated, thus making the procedure a simpler one for the physician while also reducing the added risk of infection and trauma attendant with complete replacement. Low profile conversion gastrostomy port **200** is also configured to directly connect to an enteral feeding adapter without the need for extension tubing.

Referring to FIG. **5**, gastrostomy feeding port **200** is shown which includes resilient valve member **210**, valve housing **220**, retainer cap **230**, and bolster **270**, which are collectively connected to PEG tube **250**. PEG tube **250** is a common smooth walled PEG tube which has been cut to a suitable length as part of the conversion process. Resilient valve member **210** is made of silicone rubber and has been constructed as a molded one-piece component and is preferably made from shore A 50 to 60 durometer high tear strength medical grade silicone. Resilient valve member **210** includes a diaphragm portion **211** which has a centrally located slit **216** therein. Valve member **210** further has an outer cylindrical wall portion **212** which extends downwardly from the peripheral edge of diaphragm portion **211**. Also, valve member **210** includes a contact ring **215** about diaphragm portion **211**. Contact ring **215** is more fully depicted in the top plan view of FIG. **7** which has cap **230** removed.

Referring again to FIG. **5**, valve housing **220** defines an inner passageway **229** therethrough and includes rigid compression collar portion **221** which defines receiving cavity **222**, annular seating portion **223** for seating of an adapter, and annular barb **224**. Valve housing **220** also includes a base portion **228** with annular flange **227**. Valve housing **220** should be made from a rigid biocompatible material, such as rigid PVC.

Retainer cap **230** defines a top opening **232** intersecting a passage **234** which, in turn, intersects cap cavity **236**. Preferably, opening **232**, passage **234**, and cap cavity **236** are annular. Retainer cap **230** is preferably made of a shore A **70** to **75** durometer semi-rigid PVC, but could be made from another suitable biocompatible material as well. FIG. **6** provides a top plan view of cap **230** assembled on gastrostomy port **200**.

Referring again to FIG. **5**, gastrostomy feeding port **200** also includes bolster **270** with lower surface **271** and opposing tabs **272**. Bolster **270** has an annular wall **276** which forms a chamber **278** opposing surface **271**. Chamber **278** has upper opening **277** and is configured to receive valve housing **220**. Annular wall **276** adjacent upper opening **277** forms a seal with the valve housing base **228** and abuts annular flange **227**. Bolster **270** defines a lower opening **274** intersecting chamber **278** opposite upper opening **277**. Lower opening **274** is configured to receive the severed end of PEG tube **250**. Sealing ring **275** surrounds opening **274** and reinforces it to make it suitable for press-fit sealing. Bolster **270** is configured so that sealing ring **275** stretches over annular barb **224** with PEG tube **250** thereon and

rebounds to clamp PEG tube **250** between sealing ring **275** and annular seating portion **223**. Bolster **270** is thus configured so that sealing ring **275** clamps above annular barb **224** when annular wall **276** abuts annular flange **227**. Furthermore, when so configured, annular wall **276** seals against housing base **228**. The expansive area of surface **271** helps prevent inward migration of the gastrostomy port **200** into the body of a patient. The seal at opening **274** via sealing ring **275** further acts to sealingly prevent foreign materials and fluids from migrating along the outer surface of the PEG tube **250** and into gastrostomy port **200**.

Referring to FIG. **8** as well as FIG. **5**, chamber **278** includes a lower chamber portion **278***b*. Lower chamber portion **278***b* contains pull tie **280**. Pull tie **280** is of a type known to those of skill in the art having an elongate band portion to encircle an object and an engagement mechanism to secure pull tie **280** to the object. Pull tie **280** encircles PEG tube **250** above annular barb **224** to secure it against annular seating portion **223**. Preferably, bolster **270** is made of the same silicone material as the valve member **210** and cap **230**.

To assemble the valve structure for gastrostomy port **200**, valve member **210** is "press" fit into valve housing **220** similar to the method described for gastrostomy port **100** (see FIGS. **4***a* and **4***b* and accompanying text herein), with ring **215** of valve member **210** facing upward as shown in FIG. **7**. Also, slit **216**, which is generally straight configuration, is biased towards a positively sealing closed position by the inwardly directed compressive force from collar **221** which actively biases slit **216** to positively seal valve member **210**. Compression collar **221** exerts this constant pressure or pre-load on slit **216** to prevent diaphragm portion **211** from stretching or losing its resiliency when the valve is repeatedly opened or closed.

After valve member **210** has been seated into cavity **222**, retainer cap **230** is placed on the top portion of valve housing **220** and affixed thereto by solvent cementing or such other biocompatible bonding method appropriate for joining retainer cap **230** and valve housing **220**. Cap wall **236** engages contact ring **215** of valve member **210** to seal guard against leakage under cap **230**. Once in place, retainer cap **230** does not exert any axial compressive force upon valve member **210**, which could cause distortion of the sealing arrangement. Contact ring **215** provides reinforcement about diaphragm portion **211** and so assists in preventing distortion of the sealing arrangement.

To accomplish the conversion of PEG tube **250** to a low profile feeding port, PEG tube **250** is first clamped and then severed at an appropriate length near the stoma opening. Preferably the length of the cut tube should allow for some free-play between bolster surface **271** and the portion of the PEG tube **250** entering into the stoma site. A preferred range is 1 to 5 centimeters with a more preferred range of 1.5 to 3 centimeters and a most preferred value of about 2 centimeters.

Bolster **270** is then placed on PEG tube **250** working PEG tube **250** through opening **274** until the end of the PEG tube **250** extends beyond opening **277**. Annular seating portion **223** is then inserted into PEG tube **250** until the end of PEG tube **250** goes past the annular barb **224** and rests adjacent housing base **228**. Pull tie **280** is placed about PEG tube **250** between housing base **228** and annular barb **224** and is pulled to clamp PEG tube **250** between it and annular seating portion **223** of valve housing **220**. Pull tie **280** includes a mark placed along a given length of the elongate band portion for alignment with the engagement mechanism. This mark is positioned to correspond to the proper length of pull tie **280** to assure that adequate tension is exerted to the PEG tube **250** for a reliable seal. Consequently, by aligning this mark appropriately, the proper amount of clamping force results and a reliable seal of PEG tube **250** to annular seating portion **223** is consistently obtained. Any extraneous portion of pull tie **280** is then removed by cutting and trimming the excess as close to the engagement mechanism as possible.

Next, bolster **270** is moved along PEG tube **250** until annular wall **276** abuts annular flange **227**, receiving housing base **228**, and sealing ring **275** is above annular barb **224**. Tabs **272** provide a convenient point to manipulate bolster **270**. As a result, pull tie **280** is enclosed within lower chamber portion **278***b* so that bolster **270** protects the patient from unpleasant contact therewith and at the same time provides a relatively large surface area to abut the patient's skin and shelter the passage in the patient's body which contains PEG tube **250**.

As assembled as described above, gastrostomy port **200** provides a low profile gastrostomy port with a one-way entrance valve seal accessing the central lumen of the PEG tube **250**. Gastrostomy port **200** is especially useful for directly converting a PEG tube to a low profile gastrostomy port device. Gastrostomy port **200** provides a secure and reliable connection to PEG tube **250**. Furthermore, the one-way valve only permits entry and prevents fluid from refluxing or backing up the tube and out the entrance seal. Also, gastrostomy port **200** can be directly connected to a standard enteral feeding adapter as shown in FIG. **11**, thus eliminating the need to use intermediate extension tubing.

Another embodiment of the present invention will now be described which provides a unitary fixed length low profile gastrostomy port, as illustrated in FIGS. **9**, **10**, and **11**. Specifically, gastrostomy feeding port **300** is depicted which includes resilient valve member **210**, valve housing **320**, retainer cap **330**, and main port body member **350**. Resilient valve member **210** is the same valve member depicted in FIGS. **5–7**.

Valve housing **320** defines a lower opening **329** therethrough and includes rigid compression collar portion **321** which defines receiving cavity **322**. Valve housing **320** also includes a support base portion **328** adjacent opening **329**. Valve housing **320** is injection molded from a rigid plastic such as lexan or polypropylene, but could be a machined part of stainless steel, or made of other suitable biocompatible material as well.

Retainer cap **330**, which is made of silicone or other suitable biocompatible material, defines a top opening **332** intersecting passage **334** which, in turn, intersects cap cavity **336**. Preferably, opening **332**, passage **334**, and cap cavity **336** are annular. Retainer cap **330** also defines an annular channel **338** configured to engage main port body member **350** and valve housing **320**. Retainer cap **330** is preferably made of the same material as valve member **210**.

Gastrostomy feeding port **300** also includes a unitary main port body member **350**. Main port body member **350** is made of silicone or other suitable biocompatible material and has a conical tip portion **380** connected to tubular stem portion **390** by a biocompatible adhesive solvent or cement such as RTV. Tubular stem portion **390** has a bell shaped portion **392** with a surface **394** configured for contact against the wall of the patient's stomach. Preferably the length of stem portion **390** allows for some free-play of main port body member **350** implanted in the patient's stomach. A preferred range is 1 to 5 centimeters with a more preferred range of 1.5 to 3 centimeters and a most preferred value of

about 2 centimeters. The conical tip **380** defines holes **382**. Main port body member **350** defines a passage **385** intersecting the holes **382** and a tube opening **396** in coupling portion **370**.

Tubular stem portion **390** is integrally connected to a coupling portion **370** with opposing flaps **372** which aid in the placement and manipulation of gastrostomy feeding port **300**. Coupling portion **370** has a lower surface **371** which is configured to contact the patient's skin adjacent the passage in the patient's body containing the tubular stem portion **390**. Coupling portion **370** also includes an upper annular wall **376** with an annular shelf **377**. Annular wall **376** defines a space **379** for receiving valve housing **320** and is configured to engage annular channel **338** along side compression collar **321**. The space **379** is further configured so that opening **329** aligns with tube opening **396** when the valve housing **320** is received therein.

To assemble the valve structure for gastrostomy port **300**, valve member **210** is "press" fit into valve housing **320** similar to the method described for gastrostomy ports **100** and **200**. Compression collar **321** exerts a constant pressure or pre-load on slit **216** to prevent diaphragm portion **211** from stretching or losing its resiliency after repeated use.

After valve member **210** has been seated into cavity **322**, valve housing **320** is placed into space **379** of member **350**. The conical tip **380** may be bonded to tubular stem portion **390** either before or after these steps. Next, retainer cap **330** is situated so that compression collar **321** and annular wall **376** engage annular channel **338** and retainer cap **330** abuts annular shelf **377**. Once in position, retainer cap **330** is attached to member **350** by a biocompatible adhesive, such as an RTV. When so positioned, retainer cap **330** does not exert any axial compressive force upon valve member **310** which could cause distortion of the sealing arrangement. Together, retainer cap **330** and coupling portion **370** comprise a port head **305** which contains valve housing **320** and resilient valve member **210**.

Gastrostomy port **300**, as above described and shown in FIGS. **9**, **10**, and **11**, provides a unitary fixed length low profile gastrostomy port with a one-way positively sealing entrance valve. The one-way valve permits only entrance into passage **385** and prevents any fluid from refluxing or backing up the tube and out the entrance seal. Gastrostomy port **300** can be used directly connected to a standard enteral feeding adapter as shown in FIG. **11**.

FIG. **11** shows an adapter **360** opening entrance slit **216** of valve member **210** situated in gastrostomy port **300**. Adapter **360** has a rigid injection molded body portion **361**, with a passage through a base stem portion **362** and front stem portion **363**. Connected onto base stem portion **362** is flexible PVC connecting tube **364**.

Adapter **360** directly connects to the gastrostomy port **300**. The front stem portion **363** passes through top opening **332** and opens valve member **210**. Next, front stem portion **363** passes through opening **329**, engages tube opening **396**, and extends into passage **385**. Tube opening **396** is configured so that it seals against front stem portion **363** positioned therein. Just as front stem portion **363** engages tube opening **396**, the base stem portion seats against support base **328** of valve housing **320**. Not only does support base **328** offer support to the adapter, but also prevents inserting the adapter too far into the gastrostomy port **300**. In this supported position, the top opening **332** seals against the base stem portion **362** of adapter **360**. Adapter **360** thus accesses passage **385** of member **350** to directly deliver enteral formula or the administration of liquid medication into the body of a patient having a lower seal at tube opening **396** and an upper seal at top opening **332**. Between these two seals a support base is provided which limits the extent of penetration of adapter **360** into the gastrostomy port **300** and the valve member **210** opens to allow adapter **360** to pass therethrough. When adapter **360** is removed, valve member **210** closes instantaneously to prevent reflux. Sealing is instantaneous due to compression collar **321** which acts to positively return leaves **217** and **218** to their normally closed position. Adapter **360** can be repeatedly inserted as needed over many months of use without the valve leaking or stretching out of shape.

Devices are further provided, as shown in FIGS. **12–17**, having features which enhance the atraumatic insertion and removal of the device through a stoma while also providing sufficient structure to reliably resist device pull-out. Like figure numbers for components of different embodiments in these drawings signify that the components correspond. As depicted in FIGS. **12** and **13**, the present invention includes devices **400** for insertion into a stoma S through a wall W of a body cavity C of a patient for transport of materials from the exterior of the patient to the interior of the body cavity C. The device **400** includes a port head **401**, a stem portion **490** and a retaining element **492**. The port head **401** defines a passageway **434** having a first end **435** and a second end **436**. An entrance **432** is in communication with the first end **435** of the passageway **434** for receiving a delivery device for delivery of nutrients and medicines.

FIG. **13** depicts a device similar to the port of FIG. **9** equipped with a retaining element **492** as shown in FIG. **12**. The port head **401** of this embodiment includes a resilient valve member **410**, a valve housing **420**, a retainer cap **430** and a bolster **470** having lower surfaces **471** as described above. The device **400** also includes a hollow tubular stem portion **490** having an inner end **450** and an outer end **451** attached to the port head **401**. The stem portion **490** defines a lumen **485** in communication with the second end **436** of the passageway **434**. The stem portion **490** is sized to extend through the stoma S with the port head **401** disposed on the exterior E of the patient as shown in FIG. **13**.

The device **400** also includes a retaining element **492** having an open first end **493** attached to the inner end **450** of the stem portion **490** and a closed second end **494**. The element preferably includes a support portion **464** at the first end **493** for contacting the internal surface I of a body cavity C. The retaining element **492** defines a substantially enclosed cavity **495** in communication with the lumen **485** and a hole **482** in communication with the cavity **495** for delivering materials to the interior of the body cavity C.

In one preferred embodiment, the retaining element **492** includes a conical tip **420** opposite the support portion **464** and the hole **482** is defined in this tip **420**. The retaining element **492** includes an interior surface **497** which defines a tool engaging surface **498** at the second end **494** of the retaining element **492** for engaging an insertion tool. Most preferably, the retaining element **492** includes a shoulder portion **425** which defines the support portion **464** and an annular wall portion **426** as shown in FIG. **13**. The shoulder portion includes a bend **427** between the support portion **464** and the annular wall **426**. In one preferred embodiment, the support portion **464**, the bend **427** and the annular wall **426** form an angle β which is most preferably about 90 degrees. It is to be understood that alternative configurations for the retaining element **492** are contemplated as well which may suitably serve the purposes intended.

The retaining element **492** is made of a resilient, biocompatible, elastomeric material so that it is resiliently

deformable between a normally enlarged state as shown in FIGS. **12** and **13** and a collapsed state as shown in FIG. **14** for insertion and removal through the stoma S. Any suitable resilient, biocompatible material having plastic memory is contemplated, such as polyurethane, rubber latex, styrene-butadiene-rubber latex and preferably, silicone rubber. When the stem portion **490** is inserted through the stoma S and the element **492** is in its normally enlarged state, the support portion **464** of the retaining element **492** is configured for contacting the internal surface I of the body cavity C to retain the element **492** within the body cavity C as shown in FIG. **13**.

Devices of this invention are preferably provided with means for controlling the deformation of the retaining element **492** between the normally enlarged state (FIG. **13**) for retention and the collapsed state (FIG. **14**) for insertion and removal. For this purpose, grooves **500** in the retaining element **492** controllably bias the folding of the retaining element **492** during insertion and removal while also providing sufficient structure to reliably resist pull-out of the device **400**.

In one preferred embodiment, the grooves are defined in the interior surface **497** of the retaining element **492**. Preferably, the grooves **500** are defined in the shoulder portion **425** as depicted in FIGS. **12**, **13** and **15**. In a most preferred embodiment best shown in FIG. **16**, each of the grooves **500** extend on the interior surface **497** from the annular wall **426**, through the bend **427** and onto the support portion **464**. Although the grooves **500** of the present invention bias the folding of the retaining element **492**, they do not appreciably diminish rigidity. Advantageously, this invention enhances deformation of the retaining element **492** for insertion but resists inadvertent collapse that might occur from pulling on the device **400**.

In one preferred embodiment, the retaining element defines four grooves in spaced relation, as shown in FIG. **15**. Referring again to FIG. **12**, the grooves **500** are substantially parallel to a longitudinal axis l defined by the cavity **495**. When an insertion tool is engaged to and pressed against the tool engaging surface **498** for insertion through the stoma as shown in FIG. **14**, the grooves **500** are configured, or shaped, sized and located, to controllably bias the folding and collapse of the retaining element **492** toward the longitudinal axis l. Particularly, it has been found that the retaining element will deflect inward or collapse at one or more of the grooves **500**. It is contemplated that the insertion tool can be any mandrel-like tool such as an obturator.

In the embodiment shown in FIG. **17**, each of the holes **482** are oval having a major axis α which is substantially parallel to the longitudinal axis l (FIG. **14**). The holes **482** are of any suitable size and shape which provides free delivery of materials from the cavity **495** but which still maintain the structural integrity of the retaining element **492**. In a preferred embodiment, two oppositely spaced holes **484** are defined in a conical tip portion **420** of the retaining element **492**.

It is contemplated that the embodiment of the invention shown in FIG. **12** can be equipped with any suitable port head **401** and/or stem portion **490**. For example, the retaining element **492** as shown in FIG. **12** can be placed in combination with the stem portions and port heads as shown in FIGS. **1** and **11**.

In the preferred embodiment shown in FIG. **13**, stem portion **490** and the annular wall **426** are integrally molded. The tip **420** is attachable to the annular wall **426**, such as by bonding as discussed above. As shown in FIGS. **13**, **16** and **17**, the annular wall **426** may be provided with a bonding surface **428** defined by a cut-out in the annular wall **426**. In this embodiment, the tip **420** would include a mating surface **421** defined by a complementary cut-out in the wall **422** of the tip **420** for securely attaching the tip **420** to the annular wall **426**.

Prior to insertion into a stoma, device **400** is fitted with an insertion device such as the obturator O depicted in FIG. **14**. With the valve **410**, the valve housing **420** and the retainer cap **430** removed from the port head, (see FIG. **13**) the obturator O is inserted into the passageway **434**. While the port head **401** is supported by digital contact on the lower surface **471** of the bolster **470**, the obturator O is extended through the lumen **485** of the stem portion **490** and into the cavity **495** of retaining element **492**. The pressure of the obturator O against the tool engaging surface **498** of the interior surface **497** of the retaining element **492** causes deformation of the retaining element **492**. As the device-obturator assembly is inserted through the stoma S, the traction force of the stoma S against the shoulder portion **425** in combination with the force of the obturator O against the tool engaging surface **498** is thought to cause collapse of the retaining element **492** at the grooves **500** as shown in FIG. **14**. The most beneficial results have been found when the grooves **500** extend through the bend **427** on the interior surface **497** of the shoulder portion **425** of the element **492**. The grooves **500** controllably bias the folding of the retaining element **492** to cause the uniform collapse of the retaining element **492** towards the longitudinal axis l for passage through the stoma S during insertion and removal.

With the retaining element **492** in a collapsed state as shown in FIG. **14**, it can be atraumatically inserted through the stoma S and into the body cavity C. After the retaining element **492** is inserted through the stoma and into the body cavity, the obturator O is removed. When the obturator O is removed, the retaining element **492** returns to its normal enlarged state as shown in FIG. **13**. In the normally enlarged state of the retaining element **492**, the shoulder **425** of retaining element **492** has an effective diameter d which is greater than the diameter D of the stoma S. As shown in FIG. **13**, the support portion **464** contacts the interior surface of the body cavity. Once the insertion device is removed, the valve **410**, valve housing **420** and retainer cap **430** are replaced and the port is ready to receive a delivery device. The retaining element **492** can be collapsed and atraumatically removed through the stoma S as described above for removal of the port.

As can be appreciated, a number of variations of the gastrostomy ports **100**, **200**, **300** and **400** can be made which fall within the underlying spirit of the invention. For instance, variations in form of the entrance seal can be made from that specifically described herein without departing from the spirit or scope of the underlying invention. Also, varying configurations as to the shape of the valve and corresponding valve receiving cavity, in the slit within the valve, or in the grooves within the retaining element may still fall within the spirit and scope of this invention. With the foregoing in mind, it is apparent to those skilled in the art to make modifications or different configurations of the invention without varying from the invention and the invention is not to be limited to the particular forms herein shown and described except insofar as indicated by the scope of the appended claims.

Accordingly while the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the

preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A device for insertion into a stoma through a wall of a body cavity of a patient for transport of materials from the exterior of the patient to the interior of the body cavity, comprising:

a port head defining a passageway having a first end and a second end and an entrance in communication with said first end of said passageway for receiving a delivery device;

a hollow tubular stem portion having an inner end and an outer end attached to said port head, said stem portion defining a lumen in communication with said second end of said passageway, said stem portion sized to extend through the stoma with said port head disposed on the exterior of the patient;

a retaining element having an open first end attached to said inner end of said stem portion and a closed second end, said element defining a substantially enclosed cavity in communication with said lumen and a hole in communication with said cavity for delivering materials to the interior of the body cavity, said element having an interior surface defining a tool engaging surface at said second end of said element for engaging an insertion tool;

said element being resiliently deformable between a normally enlarged state for retention and a collapsed state for insertion and removal through the stoma, said element having a support portion at said first end of said element configured for contacting the internal surface of the body cavity to retain said element within the body cavity when said stem portion is inserted through the stoma and said element is in its normally enlarged state; and

said interior surface of said element defining a first groove substantially parallel to a longitudinal axis defined by said cavity, said first groove configured to controllably bias the folding and collapse of said retaining element toward said longitudinal axis when the insertion tool is pressing against said tool engaging surface for atraumatic passage through the stoma.

2. The device of claim 1 wherein said internal surface further defines a number of grooves parallel to said longitudinal axis and in spaced relation to said first groove.

3. The device of claim 1 wherein said element includes a conical tip opposite said support portion and said hole is defined in said conical tip.

4. The device of claim 3 wherein said element includes a shoulder portion defining said support portion, an annular wall portion and a bend between said support portion and said annular wall portion, said shoulder portion defining said grooves, each said groove extending through said bend.

5. The device of claim 1 wherein said element includes a semi-spherical tip opposite said support portion and said hole is defined in said tip.

6. The device of claim 1 wherein said port head, said stem portion and said annular wall are integrally molded and said tip is attachable to said annular wall portion.

7. The device of claim 1 wherein said element is dome shaped when said element is in the enlarged state.

8. The device of claim 1 wherein said support portion is planar when said element is in the enlarged state.

9. The device of claim 8 wherein said support position, said bend and said annular wall form an angle when said element is in the enlarged state, said angle being about 90 degrees.

10. The device of claim 1 wherein said support portion is concave when said element is in the enlarged state.

11. The device of claim 1 wherein said hole is oval having a major axis, said major axis substantially parallel to said longitudinal axis.

12. The device of claim 1, wherein:

said entrance has a first diameter which allows a first distal portion of the delivery device to pass through into said passageway and which is sized to sealingly engage a larger second portion of the delivery device, said port head further defining a tube opening in communication with said second end of said passageway, said tube opening having a second diameter configured to sealingly engage the first portion of the delivery device.

13. The device of claim 1, wherein:

said port head further includes a one-way entrance valve including:

a rigid compression collar portion which defines a valve member receiving cavity;

a resilient valve member, said resilient valve member including a diaphragm portion and an outer wall portion, said diaphragm portion defining a slit therethrough and having an outer peripheral edge which generally conforms in shape to said valve member receiving cavity but is larger in dimension than said cavity when said resilient valve member is uncompressed, said outer wall portion extending away from said outer peripheral edge and generally conforming in shape to said cavity; and

wherein said resilient valve member is compressively fitted within said valve member receiving cavity by advancing said outer wall portion into said cavity to thereby cause said outer peripheral edge to be compressed in dimension to fit within said cavity, with said compression collar portion of said valve housing pressing inwardly against said outer peripheral edge of said diaphragm portion to apply laterally compressive forces against said diaphragm portion and to thereby bias said slit toward a normally closed position.

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